

### **DETAILED ACTION**

Claims 1-22, 24, and 26 are pending in the application.

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

**Group I, claim(s) 1-14, 24, and 26**, drawn to a cosmetic or dermatological composition and method for protecting against ultraviolet rays comprising a mixture of mineral screening agents and methylenebis(benzotriazolyl)tetramethylbutylphenol in the form of a water-in-oil emulsion that contains at least one emulsifier chosen from the group consisting of silicone derivatives with a glucose component comprising between 2 to 10 glucose units.

**Group II, claim(s) 15-22**, drawn to an assembly for applying a cosmetic or dermatological composition for protecting against ultraviolet rays, comprising a composition and a container for the composition, said container consisting of a reservoir and a manually-driven propulsion pump.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: There is no special technical feature. The composition of group I comprises mineral screening agents and methylenebis(benzotriazolyl)tetramethylbutylphenol in the form of a water-in-oil emulsion. The composition contains at least one emulsifier chosen from the group consisting of silicone derivatives with a glucose component comprising between 2 to 10 glucose units. The assembly, group II, for applying a cosmetic or dermatological

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composition consisting of a reservoir and a manually driven propulsion pump has a composition that comprises at least one emulsifier chosen from the group consisting of silicone derivatives with a glucose component comprising between 2 to 10 glucose units. The composition used in the assembly does not comprise the use of methylenebis(benzotriazolyl)tetramethylbutylphenol in the composition, which is a vital component of the composition in group I. Therefore, the compositions are not the same that can be used in the assembly. In addition, compositions comprising mineral screen agents and methylenebis(benzotriazolyl)tetramethylbutylphenol in the form of water-in-oil emulsions are known in the art as evidenced by the following patents: US 6,436,378, WO 02/43690, and DE 10162842. Thus, a feature found in the prior art cannot be considered to be a special technical feature.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

During a telephone conversation with Kevin McHenry on April 16, 2010 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-14, 24, and 26. Affirmation of this election must be made by applicant in

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replying to this Office action. Claims 15-22 will be withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is further reminded in order for the restriction requirement to be complete an election of a single invention from Groups I-II should be made.

Claims 1-22, 24, and 26 are pending in the Application. Claims 15-22 will be withdrawn from further consideration, as being drawn to a non-elected invention. Claims 1-14, 24, and 26 will presently be examined to the extent they read on the elected subject matter of record. Applicant's preliminary amendment filed July 7, 2007 is acknowledged.

### ***Priority***

The application is a national stage entry for PCT/FR05/00048 filed January 10, 2005, which claims priority to foreign French Application No. 0400174 filed January 9, 2004.

### ***Information Disclosure Statement***

Receipt of Information Disclosure Statements filed July 7, 2006 and August 22, 2006 is acknowledged.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-14 and 24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,919,071 ('071). Although the conflicting claims are not identical, they are not patentably distinct from each other because each application is drawn to a cosmetic or dermatological composition from protecting against ultraviolet radiation comprising a water-in-oil emulsion comprising a combination of at least one particulate inorganic screening agent (mineral screening agent) and at least one emulsifying agent chosen from the group consisting of silicone derivatives with a glucose component comprising between 2 to 10 glucose units, the particulate inorganic screening agent being uniformly dispersed in the water-in-oil emulsion and its mean particle size being between 1 and 100 nanometers,

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and the particulate inorganic screening agent being present in a proportion of from 4% to 40% by weight of the total composition. U.S. Patent No. '071 does not teach the composition comprises methylenebis(benzotriazolyl)tetramethylbutylphenol, as claimed in the instant application. However, it would have been obvious to the skilled artisan that methylenebis(benzotriazolyl)tetramethylbutylphenol could be used in the compositions because claim 14 of U.S. Patent No. '071 discloses that the composition of claim 1 further comprises at least one adjuvant chosen from the group consisting of organic sunscreens which are active in UV-A or UV-B. It is known in the art that methylenebis(benzotriazolyl)tetramethylbutylphenol is an organic sunscreen that is a UV-B sunscreensing agent and are combined with inorganic sunscreensing agents to form compositions that are protect against sun damage to the skin. For these reasons, one of ordinary skill in the art would conclude that the invention defined in the instant claims would have been an obvious variation of the invention defined in the claims of the cited US. Patent.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14, 24, and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-14 and 26 are viewed as indefinite and confusing because of Applicant's use of the terms "based on" (claim 1, line 2) and "contains". It is not readily

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apparent to the examiner exactly what applicant intends by so many of these phrases employed in the same claims to describe and define said invention. The examiner suggests terms like "comprising", "consisting of" and "consisting essentially of" to define the claimed invention.

Claim 1, line 2, recites "having the INN name". It is not necessary for Applicant to indicate that "methylenebis(benzotriazolyl)tetramethylbutylphenol" is the International Nonproprietary Name in the claim. Applicant should delete this recitation from the claim.

Claim 1 recites the limitation "the particulate inorganic screening agent" in lines 7-8. There is insufficient antecedent basis for this limitation in the claim. Applicant claims the composition is a mixture of "mineral screening agents" and "the organic screen agent". Applicant does not indicate or reference "particulate" or "inorganic screening agents". The examiner is unable to determine which component of the mixture applicant is referencing. The examiner will examine the application as the "mineral screening agents" being particulate and inorganic screening agents.

Claim 1, line 10, recites the terms "a proportion". The use of the terms "a proportion" renders the claim indefinite. A proportion is a part considered in relation to the whole. Applicant should define what the relation to the whole is or what the whole is, such as, "a proportion of from 4% to 40% by weight, relative to the total weight of the composition".

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Claim 2, line 2, uses improper Markush language. Appropriate correction is required, such as, "wherein the silicone derivative is selected from the group consisting of .....alkylsilicones".

Claim 24, lines 4 and 5, recite "the composition". It is unclear to the examiner to what "composition" Applicant is referring, when referencing "the" composition. Applicant should clarify the composition. The examiner will examine the claim as any composition that can be applied to the skin with a propulsion pump dispenser.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 24 is rejected under 35 U.S.C. 102(b) as being anticipated by Hargraves et al. (US 6,013,270).

Hargraves et al. disclose a skin care kit comprising a pump dispenser (propulsion pump bottle) and a composition (composition) useful for regulating skin condition (especially human skin, more especially human facial skin), including lubricating the skin, increasing the smoothness and suppleness of the skin, preventing or relieving dryness of the skin, hydrating the skin, and/or protecting the skin regulating visible and/or tactile discontinuities in skin, e.g., visible and/or tactile discontinuities in skin texture, more especially discontinuities associated with skin aging (col. 1, lines 3-14). Hargraves et al. disclose the dispenser may be used for any application concerned with

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the metered dispensing of skin care compositions, such as for medical applications, cosmetic and body care applications (applying the composition to the skin) (col. 20, lines 10-13). Hargraves et al. disclose a skin care product which involves a dispenser comprising a dispensing piston mechanism for extracting and dispensing such compositions from a supply container, without thereby impairing the reliability and metering accuracy of a dispenser of this type. A preferred embodiment of the present invention comprises a skin care composition contained in a dispenser such that the composition comprises an oil-in-water emulsion, a polymeric thickening agent, a reflective particulate material selected from the group consisting of  $\text{TiO}_2$ ,  $\text{ZnO}$ ,  $\text{ZrO}_2$ , and mixtures thereof (col. 20, lines 28-35).

Hargraves et al. meet all the limitations of the claim and thereby anticipate the claim.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-14 and 26 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Choulot et al. (WO 01/74294) in view of Goppell et al. (DE 101 62 842) and Lorant et al. (FR 2,817,148). U.S. Patent No. 6,919,071 is used as the English Equivalent of WO 01/74294 for translations purposes. US 7, 029,660 is used as the English Equivalent for DE 101 62 842 for translation purposes. US 2004/0076592 is used as the English Equivalent for FR 2,817,148 for translation purposes.

### **Applicant's Invention**

Applicant claims a cosmetic or dermatological composition for protecting against ultraviolet rays, comprising a mixture of mineral screening agents (particulate inorganic screening agent) and the organic screening agent, methylenebis(benzotriazolyl)-tetramethylbutylphenol. Applicant claims the composition is in the form of a water-in-oil emulsion. Applicant claims the composition contains at least one emulsifier chosen from the group consisting of silicone derivatives with a glucose component comprising between 2 and 10 glucose units. Applicant claims the particulate inorganic screening agent is uniformly dispersed in the water-in-oil emulsion and its mean particle size is between 1 and 100 nanometers.

### **Determination of the scope of the content of the prior art (MPEP 2141.01)**

Choulot et al. teach in claim 1, col. 9, lines 53-63-col. 10, lines 1-4 of the translation, a cosmetic or dermatological composition for protecting against ultraviolet radiation, comprising a water-in-oil emulsion comprising a combination of at least one particulate inorganic screening agent, chosen from the group consisting of titanium

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dioxide, zinc oxide and mixtures thereof, and at least one emulsifying agent chosen from the group consisting of silicone derivatives with a glycosidic constituent comprising a number of glucose units of between 2 and 10, the particulate inorganic screening agent being homogeneously dispersed in the water-in-oil emulsion and having a mean particle size between 1 and 100 nanometers, and the particulate inorganic screening agent being present in an amount of 6 to 40% by weight, wherein the composition has a viscosity of less than 100 Pa.s (100 000 centipoises) at 25° C. Choulot et al. teach in claim 2 of the translation, that the silicone derivative is chosen from (C<sub>2</sub>-C<sub>30</sub>) alkylsilicones and amino(C<sub>2</sub>-C<sub>30</sub>) alkylsilicones. Choulot et al. further teach in claim 3 of the translation, that the silicone derivative is ethylhexyl dimethicone ethoxy glucoside. Choulot et al. teach that the emulsifying agent is present in the compound in a proportion of between 5 to about 30% by weight, relative to the total weight of the composition. This weight range is within the claimed weight range of the instant application of 2% and about 30%. Choulot et al. teach in claim 4 of the translation that the composition further comprises cyclodimethicone. Choulot et al. teach in claims 7 and 8 of the translation, the particulate inorganic screening agent is hydrophobic titanium dioxide, or a mixture of zinc oxide and one of a) titanium dioxide doped with iron or b) hydrophobic titanium dioxide. Choulot et al. teach in claim 9 of the translation the composition further comprises at least one agent protecting against the immunosuppression induced by ultraviolet radiation, chosen from the group consisting of Aloe vera, vitamin E, the unsaponifiable component of soybean oil and mixtures thereof. Choulot et al. teach the agent against immunosuppression induced by

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ultraviolet radiation is between 0.05 and about 5% by weight, relative to the total weight of the composition. Choulot et al. teach in claims 11 and 12 of the translation, the composition further comprises at least one agent protecting the DNA of skin cells, chosen from the group consisting of isoflavones or zinc salts, both and that the agent protecting the DNA of skin cells is zinc gluconate. Choulot et al. teach the agent for protecting the skin cells is between about 0.01 and about 1% by weight, relative to the total weight of the composition (claim 13, translation). Choulot et al. teach the cosmetic or dermatological composition further comprises organic sunscreens which are active in UV-A or UV-B (claim 14) (col. 10, lines 5-61, translation). Choulet et al. teach the cosmetic or dermatological treatment of the skin intended to protect the skin against the harmfulness of and attack by ultraviolet radiation and which essentially consists in applying an effective quantity of a cosmetic or dermatological composition to the skin (col. 5, lines 66-67-col. 6, lines 1-10, translation). Choulet et al. teach the cosmetic or dermatological composition may be provided in the form of a cream, a milk, a gel, a gel cream, a lipstick, or in any other forms generally used in the cosmetic or dermatological field for the topical application of a water-in-oil emulsion, in particular those which are usually suitable for antisen cosmetic or dermatological compositions (translation).

***Ascertainment of the difference between the prior art and the claims  
(MPEP 2141.02)***

Choulet et al. do not teach that the composition comprises methylenebis (benxotriazolyl) tetramethylbutylphenol. It is for this reason Goppell et al. and Lorant et al. are added as secondary references.

Goppell et al. teach a light-protective cosmetic or dermatological preparation, comprising (a) at least benzotriazole and (b) at least one benzoxazole derivative. Goppell et al. teach the cosmetic or dermatological preparation is used in a method of protecting the skin against light-induced aging, each comprising applying the preparation to the skin (Abstract, translation). Goppell et al. teach an advantageous benzotriazole is 2, 2'-methylenebis (6-(2H-benzotriazol-2-yl)-4-(1, 1, 3, 3-tetramethylbutyl-) phenol), a broadband filter. Goppell et al. teach that the benzotriazole is available under the trade name Tinosorb® M (col. 5, lines 16-65, translation). Tinosorb® is methylenebis (benzotriazolyl) tetramethylbutylphenol. Goppell et al. teach the preparations may additionally comprise one or more water phases and be present, for example, in the form of W/O emulsions (col. 6, lines 36-45). Goppell et al. teach the use of silicone emulsifier(s) in the composition (col. 8, lines 21-31). Goppell et al. teach water soluble antioxidants may be use in the formulations, such as vitamin E and derivatives and vitamin A and derivatives (col. 12, lines 34-39, translation). Goppell et al. teach in example 4, cols. 27-28 of the translation, sprayable W/O emulsions that comprise cyclomethicone, methylenebis (benzotriazolyl) tetramethylbutylphenol, zinc oxide, and titanium dioxide.

Lorant et al. teach stable, topically applicable cosmetic/dermatological compositions, notably W/O emulsions, well suited for the UV-photoprotection of the skin, lips and/or the hair, and/or for the makeup of the skin and/or the lips, contain a thus effective amount of at least one mineral oxide having a hydrophobic coating thereon, and, as a stabilizing agent therefor, an effective amount of at least one

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oxyalkylenated polydimethylsiloxane bearing at least one glycoside residue substituent, formulated into a physiologically acceptable medium (Abstract, translation). Lorant et al. teach the metal oxides that may be used are any of those already known per se for their photoprotective activity. Lorant et al. teach they may be chosen especially from titanium oxide (titanium dioxide in amorphous form or crystallized in rutile and/or anatase form) and zinc oxide (page 2, paragraph 38, translation). Lorant et al. teach these metal oxides may be in the form of micrometer-sized particles or nanometer-sized particles (nanopigments). In the form of nanopigments, the mean particle sizes range, for example, from 5 to 100 nm (page 2, paragraph 39, translation). Lorant et al. teach the coated metal oxides are chosen from titanium oxides and zinc oxides (page 2, paragraph 41, translation). Lorant et al. teach these hydrophobic coated titanium oxides and nanotitanium oxides may be in the form of a solid filler or in the form of a dispersion in an oily medium (page 3, paragraph 60, translation). Lorant et al. teach the composition may constitute, for example, a lotion, a milk or a cream that is relatively fluid. It may even be very fluid without being destabilized. The expression "very fluid" means herein a composition having a viscosity ranging from about 60 to 600 cPois (page 3, paragraph 67, translation). Lorant et al. teach one preferred embodiment the composition comprises at least one sunscreen. As sunscreens, the composition of the invention may comprise any UVA and UVB screening agents that may be used in cosmetics (page 4, paragraph 75, translation). Lorant et al. teach examples of UV-A agents that may be used include triazine derivatives, and in particular 2,2'-methylenebis[6-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol] sold by Ciba

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Geigy under the name Tinosorb M (page 6, paragraph 124, translation). Tinosorb M is methylenebis(benzotriazolyl)tetramethylbutylphenol. Lorant et al. teach the cosmetic use of the composition is for the antisun care and/or protection of the skin, the lips and/or the hair, and/or for making up the skin and/or the lips (page 6, paragraph 128, translation).

***Finding of prima facie obviousness  
Rationale and Motivation (MPEP 2142-2143)***

It would have been obvious to one of ordinary skill in the art at the time of invention to use the teachings of Choulet et al., Goppell et al., and Lorant et al. and use methylenebis(benzotriazolyl)tetramethylbutylphenol in the formulation. Choulet et al. teach that UV-A and UV-B formulations may be added to the formulations comprising, a water-in-oil emulsion comprising a combination of at least one particulate inorganic screening agent, chosen from the group consisting of titanium dioxide, zinc oxide and mixtures thereof, and at least one emulsifying agent chosen from the group consisting of silicone derivatives with a glycosidic constituent comprising a number of glucose units of between 2 and 10 that's used to protect the skin against the harmfulness of and attack by ultraviolet radiation. One skilled in the art at the time the invention was made would have been motivated to use methylenebis(benzotriazolyl)tetramethylbutylphenol in the formulations as the additional UV-B agent because the prior art, Goppell et al. and Lorant et al., each teach the use of methylenebis(benzotriazolyl)tetramethylbutylphenol combined with particulate inorganic screening agents in water-in-oil emulsions as antisun care and photo-protection products for the skin. In addition, in view of *In re Kerkhoven*, 205 USPQ 1069 (C.C.P.A.

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1980), it is *prima facie* obvious to combine two or more compositions each of which is taught by prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in prior art, thus claims that requires no more than mixing together two or three conventional UV-A and UV-B agents (sunscreens) set forth *prima facie* obvious subject matter.

Therefore, the claimed invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made because every element of the invention has been fairly suggested by the cited reference.

None of the claims are allowed.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andriae M. Holt whose telephone number is (571)272-9328. The examiner can normally be reached on 7:00 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richter Johann can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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